AUG 4 2000

K000653

Pulmonox™

Pulmonox™
Medical Corporation

Section16.0
510(k) Summary

Date:
February 9, 2000

Submitter:
Pulmonox Medical Corporation
P.O. Box 1020
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Contact Information:
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Trade Name:
AeroNOx® Portable Nitric Oxide Titration and Monitoring System

Common Name:
Nitric Oxide Delivery System

Classification Name:
Nitric Oxide Administration Apparatus, Nitric Oxide Gas Analyzer, Nitrogen Dioxide Gas Analyzer, Nitric Oxide Administration Device For Use As A "Back Up"

Device to which Substantial Equivalence is claimed:
Ohmeda INOvent® Delivery System (K974562)

Intended Use:
The AeroNOx is designed to deliver a constant flow of nitric oxide gas into the breathing circuit of a continuous or near continuous flow ventilator or other respiratory gas administration systems, or a flow inflating manual resuscitator in order to provide a near constant concentration of therapeutic inhaled nitric oxide gas to patients. It is also designed to monitor nitric oxide, nitrogen dioxide and oxygen gas from a patient's ventilator or other respiratory gas administration system tubing or a flow inflating manual resuscitator prior to patient delivery.

The AeroNOx is designed for transport applications. It is intended to be used for air and ground transports as well as for transports within the hospital.

Device Description:

The AeroNOx® is designed to be a portable nitric oxide delivery device for the administration of therapeutic doses of inhaled nitric oxide. The AeroNOx® incorporates both a delivery component and an analysis component.

The delivery component is designed to deliver a constant flow of nitric oxide gas into the main gas stream of a constant flow ventilator or a modified flow inflating manual resuscitator (see "AeroNOx® Bagger" and "INOstat Bagger" below). The nitric oxide gas is titrated into the ventilator's gas delivery tubing at a point at least 30cm upstream of the gas analysis port to ensure adequate gas mixing prior to patient delivery. In this way, the concentration of nitric oxide gas that the patient receives will be at a constant concentration. Nitric oxide gas flow into the flow inflating manual resuscitator is titrated into the tubing which supplies the bulk gas flow to the resuscitator. The distance between nitric oxide titration and gas analysis port for both the AeroNOx® Bagger and INOstat Bagger is 216 cm (85 inches).

The analysis component of the AeroNOx® is designed to measure nitric oxide, nitrogen dioxide and oxygen from the ventilator tubing or flow inflating manual resuscitator on the inspiratory side, prior to patient administration. The analysis system consists of one nitric oxide electrochemical cell, one nitrogen dioxide electrochemical cell, one galvanic oxygen sensor, and a pump to draw the gas sample from the ventilator's bulk gas flow for analysis within the block that mounts the sensors. Once the gas sample has passed through the gas-sampling block, it exits the unit and is vented to room air. Analysis is to the nearest part per million (ppm) for nitric oxide, to the nearest tenth of a ppm for nitrogen dioxide and to the nearest tenth of a percent for oxygen.

In addition, two variations of a modified flow inflating manual resuscitator are available to use as back-up systems in the event of ventilator failure, AeroNOx® failure, or a combination of these two. These are described below:

1. The "AeroNOx® Bagger" flow inflating manual resuscitator is designed for use with the AeroNOx®. It can be used completely independent of the ventilator.
2. The "INOstat Bagger" flow inflating manual resuscitator is designed to be used in conjunction with a regulator with a fixed output flow in order to supply a constant nitric oxide dose completely independent of the AeroNOx® and ventilator.

Both resuscitators are disposable, single patient use devices which are available in packages of five (5). The "INOstat Bagger" will be made available as part of an "INOstat Kit" which will include one (1) "INOstat Bagger" and one fixed output regulator. Both systems are described in further detail in Section 3 of this application, Device Description.

The AeroNOx® is available in three configurations in order to address the user's needs in a cost-effective manner:

1. AeroNOx® Universal
2. AeroNOx® Bedside
3. AeroNOx® Transport

Each system will contain the following components:

Table #16.1

AeroNOx® Universal	AeroNOx® Bedside	AeroNOx® Transport
1. AeroNOx® **2. Calibration kit** **3. Universal power supply** **4. Medical grade power cord** **5. AeroNOx® "NO WORRIES" connector sample pak** **6. AeroNOx® operating manual** **7. Cylinder cart** **8. AeroNOx® mounting block** **9. Delivery regulator (RH)** **10. Delivery Regulator (LH)** 11. Transport Kit	**1. AeroNOx®** **2. Calibration kit** **3. Universal power supply** **4. Medical grade power cord** **5. AeroNOx® "NO WORRIES" connector sample pak** **6. AeroNOx® operating manual** **7. Cylinder cart** **8. AeroNOx® mounting block** **9. Delivery regulator (RH)** **10. Delivery Regulator (LH)** 11. Stainless steel hose with quick connect fittings	**1. AeroNOx®** **2. Calibration kit** **3. Universal power supply** **4. Medical grade power cord** **5. AeroNOx® "NO WORRIES" connector sample pak** **6. AeroNOx® operating manual** 7. Transport Kit

** Items common to all three configurations are in bold type

Comparison of Technological Characteristics:

The following table compares the technological characteristics of the AeroNOx® to that of the INOvent® to which the AeroNOx® is claiming substantial equivalence.

Table 16.2

Characteristic	INOvent®	AeroNOx®
Intended Use	Delivery and analysis of therapeutic concentrations of nitric oxide gas	Delivery and analysis of therapeutic concentrations of nitric oxide gas
Analysis	Side stream analysis	Side stream analysis
Sample Flow Rate	230 ml/min	150 ml/min
Gas detection	NO: electrochemical NO2: electrochemical O2: Galvanic	NO: electrochemical NO2: electrochemical O2: Galvanic
Delivery	By Injector Module. Near	By continuous flow. Near

	constant concentration of nitric oxide gas ensured by the fact that delivery flow is proportional and in response to carrier gas flow	constant concentration of nitric oxide gas ensured by specifying use with continuous flow ventilators or other respiratory breathing apparatus only.
Battery Back Up	30 minutes	6 hours
Able to transport patients while using the device	yes	yes
Gas specific connections	- CGA 626 fittings for delivery regulators - CGA 625 fittings for calibration regulators - Standard respiratory gas connection sizes for delivery connection to patient circuit	- CGA 626 fittings for delivery regulators - CGA 625 fittings for calibration regulators Standard respiratory gas connection sizes for delivery connection to patient circuit
Delivery gas termination upon analysis of toxic concentrations of NO gas	yes	Yes Delivery gas is re-started once levels are restored to pre-termination conditions
"Back Up" System with fixed delivery concentration available	yes	yes
High and low adjustable alarms	NO: yes NO2: high only O2: yes	NO: yes NO2: high only O2: not incorporated into the device, external oxygen analyzer with alarms must be utilized. MSA MiniOX® 3000 specified in labeling
Construction Materials	Parts which come into contact with the delivery gas are nitric oxide compatible and do not form toxic substances when exposed to nitric oxide gas	Parts which come into contact with the delivery gas are nitric oxide compatible and do not form toxic substances when exposed to nitric oxide gas
Electrical Safety	UL2601-1 certified	IEC 60601-1-2 certified

Non-clinical testing:

Non-clinical testing for the AeroNOx® was completed in accordance with the Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer released by the ODE Anesthesiology, Respiratory and Defibrillator Group, Division of Cardiovascular, Respiratory and Neurological Devices on January 11, 2000.

All testing was performed per the recommendations of the Guidance Document where applicable and where not applicable, an explanation as to how the AeroNOx® met safety and efficacy concerns was addressed.

Conclusions:

Based on the information outlined in this summary, Pulmonox Medical Corporation feels that the AeroNOx® is substantially equivalent to the INOvent® when used with continuous flow ventilators or other respiratory breathing apparatus which utilize continuous flow.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Ms. Paula Tomat
Pulmonox Medical Inc.
P.O. Box 1020
5243 - 53 Avenue
Tofield, Alberta, Canada T0B 4J0

Re: K000653
AeroNOx Nitric Oxide Titration and Monitoring System
Regulatory Class: II (two)
Product Code: MRN, MRO, MRP, MRQ
Dated: June 29, 2000
Received: July 3, 2000

Dear Ms. Tomat:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K000653

DEVICE NAME: AeroNox

INDICATIONS FOR USE:

"The AeroNOx is intended to provide a constant controlled concentration of nitric oxide in breathing gas by delivering a constant controlled flow of nitric oxide into the inspiratory limb of a mechanical ventilator that operates using a continuous constant flow of fresh gas into the inspiratory limb of the ventilator. The AeroNOx is also intended to be used with a flow inflating manual ventilator (an AeroNOx accessory), by introducing controlled flows of nitric oxide into the fresh gas flow to the manual ventilator. It is also intended to monitor nitric oxide, nitrogen dioxide, and oxygen concentrations in the breathing gas.

The AeroNOx is intended to be used within a hospital or during air or ground transport outside of the hospital."

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson
Division of Cardiovascular & Respiratory Devices
510(k) Number K000653

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-